

MR1035-1346

Appl. No. 10/720,206

Response to Final Office Action dated 25 January 2006

REMARKS/ ARGUMENTS

This is a full and timely response to the outstanding final Office Action mailed January 25, 2006. Reconsideration and allowance of the application and presently pending claims, as amended, are respectfully requested.

Present Status of Application

Upon entry of the amendments in this response, claims 38-57 are now pending in the present application. More specifically, claims 38, 39, 45, and 52 correspond to amended versions of original claims 23, 24, 31, and 36. These amendments and additions are specifically described hereinafter. It is believed that the foregoing amendments and additions add no new matter to the present application.

The Office Action rejected claim 23 under 35 USC §102(b) as being anticipated by Marshall US 4,205,680 (hereinafter Marshall).

The Office Action rejected claims 24-37 under 35 USC §103(a) as being unpatentable over Marshall in view of DeBusk US 5,792,128 (hereinafter DeBusk).

No new matter has been added to the application by the amendments made herein. For at least the following reasons, it is submitted that all claims of this application are in condition for allowance. Reconsideration of the present application, as amended, is respectfully requested.

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Summary of Present Invention:

A surgical towel with x-ray detectable material which eliminates the need for re-entry into a patient after operating in situations where operating towels are missing. The surgical towel comprises a sheet of fabric having x-ray detectable material sewn inside the hem, woven into or otherwise attached to the fabric. The hem is stitched with a thread of a different color than the color of the fabric to make the towel easily identifiable as being x-ray detectable. The x-ray detectable material can easily be observed by medical personnel upon examination of an x-ray. If no x-ray detectable material is observed, unnecessary re-entry into the patient is prevented.

Response to Claim Rejections Under 35 USC Section 102

Claim 23 (corresponding to Claim 38) has been rejected under 35 USC Section 102(b) as purportedly being anticipated by Marshall.

Independent Claim 38 recites:

A surgical towel, comprising:

a sheet of woven fabric comprising at least one stitched hem;

a thread of a different color than a color of the fabric for stitching the hem, *the thread color visually identifying the surgical towel as x-ray detectable;*
and

at least one piece of x-ray detectable material attached to the fabric by the thread, the x-ray detectable material protruding from the hem allowing visual identification of the x-ray detectable material's location, *the x-ray detectable*

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material comprising identifying characteristics to identify an x-rayed object as a surgical towel.

Independent claim 38 is allowable for at least the reason that Marshall does not disclose, teach or suggest the features that are highlighted in claim 38 above.

More specifically, Marshall does not teach using a thread of a different color than a color of the fabric for stitching the hem. Marshall discloses stitching the plies of the sponge together with cotton thread along a full peripheral hem (column 2, lines 48-51).

Additionally, since Marshall does not teach using a thread of a different color, the color of the thread for stitching the hem of Marshall's medical sponge cannot visually identify the sponge as incorporating x-ray detectable material. Marshall's medical sponge does not provide any means of visually identifying the article as having x-ray detectable material incorporated into the medical sponge. In use, a surgeon or other medical personnel would have no way of visually knowing whether or not they were using an article with an x-ray detectable material incorporated into the article versus an article without such material added. This would put the patient at risk if it was assumed that the article did incorporate an x-ray detectable element when in actuality it did not incorporate such element. Also, medical personnel would have to x-ray the towel separately in order to determine that the article was in fact, x-ray detectable. This is impractical and expensive.

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It is vitally important for the doctor to readily know that he is definitely using a towel with x-ray detectable material so that the doctor can immediately use the towel without having to worry whether the x-ray detectable material is present in the towel or not.

It is important to note that the colored thread itself is not the x-ray detectable material. The thread is typically made of cotton or some other yarn/thread. This thread is what is used as the normal stitching around the towel though of a different color than the towel.

Furthermore, Marshall does not teach *"the x-ray detectable material comprising identifying characteristics to identify an x-rayed object as a surgical towel"* as recited in claim 38. Marshall's article has an elongated, flexible strand as an indicator element disposed in the handle (column 3, lines 12-14). Even if Marshall's sponge is detected by x-ray, medical personnel cannot identify the article as a surgical towel or other article. The elongated strand does not and cannot identify what the detected object is. If Marshall's sponge was detected by x-ray, the doctor would have to re-enter the patent in order to determine what the detected object is. This could severely harm the patient or greatly increase the patient's discomfort and the patient's risk of infection.

However, the present invention provides a surgical towel with x-ray detectable material, *the x-ray detectable material comprising identifying characteristics to identify an x-rayed object as a surgical towel*. This allows medical personnel to easily identify whether or not the x-ray detected object is a surgical towel. For example, if the x-ray detectable material is star-shaped, the

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star shape would allow the x-ray detected object to be easily identified as a surgical towel.

Should a towel be left in the body, it is vitally important for the doctor to know exactly what that item is. If it is a small gauze or lap sponge, the doctor might feel more secure leaving this in the body until the next planned surgery, or can wait for several days or weeks, giving the patient a chance to recuperate from the last surgery before going back in to remove the foreign object. If the doctor knows they have left an OR towel inside the body, the doctor knows that this item is much larger than either a gauze or lap sponge, and depending on the location of the item may wish to remove the item immediately as to not interfere with the normal body processes or patient healing or wait until the patient has recuperated.

In situations where multiple operations are required, identifying the x-ray detected object would allow medical personnel to determine the level of urgency required to re-enter the patient. This decreases expenses and unnecessary emergencies and improves patient's comfort and safety, while at the same time reduction the patient's risk of infection.

Without the use of an x-ray detectable material with identifying characteristics, such as Marshall's article, it is impossible for the doctor to know what has been left in the body by using a simple x-ray. This could have severe health consequences for the patient and put the patient at risk.

Consequently, Marshall does not anticipate claim 38 and the rejection should be withdrawn.

Because independent claim 38 is allowable over the prior art of record, its

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dependent claims 39-44 are allowable as a matter of law, for at least the reason that these dependent claims contain all features/elements/steps of their respective independent claim 38. *In re Fine*, 837 F.2d 1071 (Fed. Cir. 1988). Additionally and notwithstanding the foregoing allowability of these dependent claims, the dependent claims recite further features and/or combinations of features (as is apparent by examination of the claim itself) that are patentably distinct from the prior art of record.

Response to Claim Rejections Under 35 USC Section 103

Claims 24-37 (corresponding to Claims 39-57) have been rejected under 35 USC Section 103(a) as purportedly being unpatentable over Marshall in view of DeBusk.

Independent Claim 38 recites:

A surgical towel, comprising:

a sheet of woven fabric comprising at least one stitched hem;

a thread of a different color than a color of the fabric for stitching the hem, *the thread color visually identifying the surgical towel as x-ray detectable*; and

at least one piece of x-ray detectable material attached to the fabric by the thread, the x-ray detectable material protruding from the hem allowing visual identification of the x-ray detectable material's location, *the x-ray detectable material comprising identifying characteristics to identify an x-rayed object as a surgical towel*.

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As noted above, Marshall does not anticipate independent claim 38. Additionally, independent claim 38 is allowable for at least the reason that the combination of Marshall and DeBusk does not disclose, teach or suggest the features that are highlighted in claim 38 above.

More specifically, DeBusk does not teach using a thread of a different color than a color of the fabric as recited in claim 38. Furthermore, DeBusk's article has the same disadvantage as Marshall's in that it is impossible to visually determine that the article is x-ray detectable.

In the present invention as recited in claim 38, the thread color indicates that the towel is x-ray detectable and can be seen by the doctor just by looking at it. Both DeBusk and Marshall require that the article be x-rayed in order to know whether or not the article is x-ray detectable.

Furthermore, DeBusk discloses encasing an x-ray detectable element into the hem. DeBusk does not teach that "the x-ray detectable material protruding from the hem allowing visual identification of the x-ray detectable material's location" as recited by claim 38. In DeBusk, the location of the x-ray detectable element is unknown. It is vitally important for the doctor to know where the x-ray detectable element is placed relative to the body cavity. With DeBusk, the doctor would have no way of knowing.

The doctor needs to be aware of where the x-ray material is located on the towel so as to avoid unnecessary x-rays due to numerous factors. Excessive x-rays are not good for the patient's health. X-rays are also wasteful from a cost perspective due to x-ray cost and wasted labor. If the doctor doesn't know he's using an x-ray detectable towel and he

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sees the x-ray material on the x-ray itself, the doctor might think this material is actually inside the body and go in after it. For example, imagine an OR towel laid out over a body with the x-ray element unknowingly placed in the middle of the body cavity. An x-ray is taken and the doctor thinks there is a wire element inside the patient when in actuality it is in the towel that is laid over the body. To make matters worse, the doctor then has to move things around inside the body cavity looking for something that is not there and thus risking more damage to the patient than was necessary.

However, with the present invention as recited in claim 38, the x-ray detectable material protrudes from the hem, allowing visual identification of the x-ray detectable material's location. Neither Marshall nor DeBusk disclose this limitation. By applying our method, the doctor may properly position the towel so that the x-ray detectable material will not be observable during an x-ray and thus avoid jeopardizing the patient's health or at minimum the doctor would know that the OR towel did have x-ray detectable material and where it was placed so that if it showed up on an x-ray, the doctor would readily know what the indication on the x-ray was from.

Furthermore, DuBusk like Marshall fails to teach *the x-ray detectable material comprising identifying characteristics to identify an x-rayed object as a surgical towel*. Even if detected, the doctor would have no way of knowing that the detected object was a surgical towel. DeBusk and Marshall use elongated threads. This shape does occur in the human body as well as in the shape of other medical equipment such as a needle.

However, with the present invention, the x-ray detectable material has identifying characteristics that identify the surgical towel as a surgical towel. For example, the x-ray detectable material could be shaped such as triangular, square, star, etc. These shapes do

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not naturally occur in the human body. Alternatively, the x-ray detectable material could be coded, such as numbered. In these examples, the doctor would immediately know what the detected object was by observing the identifying characteristics of the x-ray detectable material seen in the x-ray.

It should be noted that Marshall's lap sponge and DeBusk's towel are different. The lap sponge is used inside the body cavity to absorb blood. A lap sponge has the loop for the doctor to hold onto so as not to lose the sponge inside the body. Lap sponges are only near the body when the doctor specifically picks one up off of the tray and uses it. These are not left near the body in order to avoid the risk of the loop being caught on something or inadvertently moved into the body cavity which would have a negative impact on the patient's health.

The operating room towel is designed to be laid out around the incision area. It is not meant to be used in the body. The doctor *would not allow* for an OR towel to have a loop handle on it like Marshall's sponge because such could be hooked or caught on something during the procedure and thus pose a risk to the patient as the OR towel is sitting on the body and cannot risk being tugged or pulled inadvertently.

As a result, one skilled in the art would not combine Marshall with DeBusk.

Therefore, Marshall in view of DeBusk do not anticipate claim 38 and the rejection should be withdrawn.

Because independent claim 38 is allowable over the prior art of record, its dependent claims 39-44 are allowable as a matter of law, for at least the reason that these dependent claims contain all features/elements/steps of their respective independent claim 38. *In re Fine*, 837 F.2d 1071 (Fed. Cir. 1988). Additionally and notwithstanding the

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foregoing allowability of these dependent claims, the dependent claims recite further features and/or combinations of features (as is apparent by examination of the claim itself) that are patentably distinct from the prior art of record.

Independent claim 45 recites:

A surgical towel comprising:

a sheet of single-ply woven cotton fabric having four edges;

at least one hem stitched in at least one of the four edges;

a thread of a different color than a color of the cotton fabric for stitching the at least one hem, the color of the thread visually identifying the surgical towel as x-ray detectable; and

at least one piece of x-ray detectable material attached to the fabric by the thread, the x-ray detectable material protruding from the hem allowing visual identification of the x-ray detectable material's location, the x-ray detectable material comprising identifying characteristics to identify an x-rayed object as a surgical towel.

Independent claim 45 is allowable for at least the reason that Marshall in view of DeBusk does not disclose, teach or suggest the features that are highlighted in claim 45 above.

The same arguments made above in regard to claim 38 apply to claim 45.

Consequently, Marshall in view of DeBusk does not anticipate claim 45 and the rejection should be withdrawn.

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Because independent claim 45 is allowable over the prior art of record, its dependent claims 46-51 are allowable as a matter of law, for at least the reason that these dependent claims contain all features/elements/steps of their respective independent claim 45. *In re Fine*, 837 F.2d 1071 (Fed. Cir. 1988). Additionally and notwithstanding the foregoing allowability of these dependent claims, the dependent claims recite further features and/or combinations of features (as is apparent by examination of the claim itself) that are patentably distinct from the prior art of record.

Independent claim 52 recites:

A surgical towel comprising:

a sheet of single-ply woven cotton fabric having four edges;

at least one hem stitched in at least one of the four edges;

a thread of a different color than a color of the cotton fabric for stitching the at least on hem, the color of the thread visually identifying the surgical towel as x-ray detectable; and

at least one piece of x-ray detectable material *through which the hem stitching is sewn*, the x-ray detectable material *protruding from the hem but not extending past an edge of the fabric*, allowing visual identification of the x-ray detectable material's location, the x-ray detectable material *comprising identifying characteristics to identify an x-rayed object as a surgical towel.*

Independent claim 52 is allowable for at least the reason that Marshall in view of

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DeBusk does not disclose, teach or suggest the features that are highlighted in claim 52 above.

The same arguments made above in regard to claim 38 apply to claim 52.

Furthermore, neither Marshall nor DeBusk disclose at least one piece of x-ray detectable material *through which the hem stitching is sewn*. DeBusk encloses material inside the roll of the hem. Marshall encloses the material in a loop handle and the loop handle is attached to the sponge.

Additionally, Neither Marshall nor DeBusk disclose the x-ray detectable material *protruding from the hem but not extending past an edge of the fabric*. DeBusk encloses material inside the roll of the hem. Marshall's loop handle extends far past the edge of the material. However, in the present invention as clearly shown in Figure 2, the material protrudes from the hem and does not extend past an edge of the fabric as recited in claim 52.

Consequently, Marshall in view of DeBusk does not anticipate claim 52 and the rejection should be withdrawn.

Because independent claim 52 is allowable over the prior art of record, its dependent claims 53-57 are allowable as a matter of law, for at least the reason that these dependent claims contain all features/elements/steps of their respective independent claim 52. *In re Fine*, 837 F.2d 1071 (Fed. Cir. 1988). Additionally and notwithstanding the foregoing allowability of these dependent claims, the dependent claims recite further features and/or combinations of features (as is apparent by examination of the claim itself) that are patentably distinct from the prior art of record.

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For at least these reasons, Applicant respectfully submits that all pending claims
patently define over Marshall and DeBusk.

CONCLUSION

For at least the foregoing reasons, it is believed that all pending claims 38-57 are
in proper condition for allowance. If the Examiner believes that a telephone conference
would expedite the examination of the above-identified patent application, the Examiner
is invited to call the undersigned.

**This Amendment was prepared by Applicant, and is being submitted without
substantive change by the undersigned Attorney.**

Respectfully submitted,
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21 April 2006
Date